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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,447	02/06/2002	Kurt R. Gehlsen	MAXIM.073DVIC1	1030
20995	7590	12/28/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			JONES, DAMERON LEVEST	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/068,447

Applicant(s)

GEHLSSEN, KURT R.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26, 28-30, 32 and 45-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 26, 28-30, 32, and 45-48 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **RESTRICTION INTO GROUPS**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 26, 28-30, 32, and 45-48 are, drawn to a method of making a cosmetic composition that inhibits the production and release of enzymatically produce ROMs from herpes labialis, herpes genitalis, and herpes zoster, classified in class 424, subclass 401.
  - II. Claims 26, 28-30, 32, and 45-48 are, drawn to a method of making a cosmetic composition that inhibits the production and release of enzymatically produce ROMs from varicella zoster, classified in class 424, subclass 401.
  - III. Claims 26, 28-30, 32, and 45-48 are, drawn to a method of making a cosmetic composition that inhibits the production and release of enzymatically produce ROMs bacterial infections, classified in class 424, subclass 401.
  - IV. Claims 26, 28-30, 32, and 45-48 are, drawn to a method of making a cosmetic composition that inhibits the production and release of enzymatically produce ROMs from chemotherapy induced mucositis, classified in class 424, subclass 401.
  - V. Claims 26, 28-30, 32, and 45-48 are, drawn to a method of making a cosmetic composition that inhibits the production and release of enzymatically produce ROMs from radiation induced mucositis, classified in class 424, subclass 401.

- VI. Claims 26, 28-30, 32, and 45-48 are, drawn to a method of making a cosmetic composition that inhibits the production and release of enzymatically produce ROMs from photodermatitis, classified in class 424, subclass 401.
- VII. Claims 26, 28-30, 32, and 45-48 are, drawn to a method of making a cosmetic composition that inhibits the production and release of enzymatically produce ROMs from thermal burns, classified in class 424, subclass 401.
- VIII. Claims 26, 28-30, 32, and 45-48 are, drawn to a method of making a cosmetic composition that inhibits the production and release of enzymatically produce ROMs from cosmetic surgery, classified in class 424, subclass 401.
- IX. Claims 26, 28-30, 32, and 45-48 are, drawn to a method of making a cosmetic composition that inhibits the production and release of enzymatically produce ROMs from periodontal disease, classified in class 424, subclass 401.

**Note:** Claims appearing in more than one group will only be examined to the extent that they read on the elected invention.

- 2. The inventions are distinct, each from the other because of the following reasons:

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Inventions I-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compounds (e.g., histamine, histamine dihydrochloride, histamine diphosphate, or other histamine salts, esters, prodrugs, serotonin, 5HT agonists, and compounds that promote the release of endogenous histamine stores) may be used to treat ROM mediated damage to the skin caused by various disorders such as herpes labialis, herpes genitalis, herpes zoster, varicella zoster, bacterial infections, chemotherapy induced mucositis, radiotherapy-induced mucositis, photodermatitis, thermal burns, cosmetic surgery, and periodontal disease. Thus, prior art that anticipates or renders obvious one of the disorders as set forth by the various groups above would neither anticipate nor render obvious another group (e.g., herpes (an inflammatory disorder) would not render obvious varicella zoster (associated with chicken pox), chemotherapy induced mucositis, radiotherapy induced mucositis, photodermatitis, thermal burns, cosmetic surgery, or periodontal disease). Hence, a separate search of each group is necessary even though the groups classify the same. Furthermore, the searching of all the invention would be a burden on the Examiner since one disorder would neither anticipate nor render another obvious.

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3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

#### **ELECTION OF SPECIES**

4. Claims 26, 28-30, 32, and 45-48 are generic to a plurality of disclosed patentably distinct species comprising various compounds selected from histamine, histamine dihydrochloride, histamine diphosphate, other histamine salts, esters, prodrugs, histamine receptor agonists, serotonin, 5HT agonists, and compounds that promote the release of endogenous histamine stores which are relevant to various disorders such as herpes labialis, herpes genitalis, herpes zoster, varicella zoster, bacterial infections, chemotherapy induced mucositis, radiotherapy-induced mucositis, photodermatitis, thermal burns, cosmetic surgery, and periodontal disease. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

**Note:** Applicant is respectfully requested to identify a **specific** compound from within the elected group above.

5. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35

U.S.C. 103(a) of the other invention.


6. Due to the complexity of the restriction requirement, a telephone call was not made to request an oral election to the above restriction requirement.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones  
Primary Examiner  
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December 22, 2005